K002507

SECTION 2. 510(k) SUMMARY

MAR 21 2001

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ARROW INTERNATIONAL

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Submitter

Arrow International
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Contact person:

Thomas D. Nickel
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Date summary prepared:

Device trade name: Two-Lumen Central Venous Access Kit with Hemostasis Valve/Side Port

Device common name: Two-Lumen Central Venous Access device

Device classification name: DBY, Class II at 21 CFR 870.1340, Introducer Catheter

Legally marketed devices to which the device is substantially equivalent:

1. K780532: Arrow Percutaneous Sheath Introducer Kit
2. K970864: Arrow-Howes™ Large Bore Multi-Lumen Central Venous Catheter
3. K981909: Baxter Multiple-Lumen Access Products

Description of device:

The proposed device is a modification to Arrow's PSI catheter with an additional lumen for central venous access. This design maintains high flows through the two lumens while passing an up to 8 Fr. thermodilution catheter, or similar device.

The catheterization kit components are configured in a high-impact polystyrene (HIPS) tray, sealed with a Tyvek® lidstock, and sterilized.

Intended use of the device:

The Arrow Two-Lumen Central Venous Access device permits venous access and catheter introduction to the central circulation.

Technological characteristics:

The proposed device has the same technological characteristics as the predicate devices.

Performance tests:

The following performance tests are included in the submission:

1. Tensile
2. Leak
3. Elongation
4. Flow Rate with Catheter
5. Flow Rate without Catheter
6. Priming Volume
7. Flex
8. Burst

Conclusions:

The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2001

Mr. Thomas D. Nickel
V.P. of Regulatory Affairs and Quality Assurance
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K002507
Trade Name: Two-Lumen Central Venous Access Kit with Hemostasis Valve/Side Port
Regulatory Class: II and II
Product Code: DYB and FOZ
Dated: January 8, 2001
Received: January 9, 2001

Dear Mr. Nickel:

This letter corrects our substantially equivalent letter of March 21, 2001 regarding the product code. The correct code is DYB not DBY as stated in the Agency letter.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA)

may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note that the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 11. INDICATIONS

510(k) Number (if known) K002507

Device Name: Two-Lumen Central Venous Access Kit with Integral Hemostasis Valve/Side Port.

Indications for Use: The Arrow Two-Lumen Central Venous Access device permits venous access and catheter introduction to the central circulation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cascarito

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002507